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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,545	05/18/2005	Eric Ferrandis	427.096	7587

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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,545	FERRANDIS, ERIC	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-22 are all the pending claims subject to unity of invention analysis.

2. Claims 12 and 13 are drawn to "As medication" which is unclear as to whether the intended subject matter is for a composition or a pharmaceutical composition. Clarification is requested especially in view of Claims 14 and 15, and Claims 19 and 20 as being drawn to pharmaceutical compositions.

3. As "use" claims, Claims 16 and 17 are drawn to non-statutory subject matter under 35 U.S.C. §101. The claims have been withdrawn from the unity of invention analysis and from restriction. Applicants are invited to bring the claims into condition for examination under U.S. practice.

Lack of Unity: Restriction

4. Restriction is required under 35 U.S.C. 121 and 372.

The claims of the present application relate to an isolated polynucleotide comprising the sequence of SEQ ID NO:8 and one or more its fragments.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same technical features, can be recognized, the requirements of unity of invention are said to be met.

Fragments corresponding to and sharing sequence homology to a sequence comprising the sequence SEQ ID NO:8 would be expected to be found in a random

universal primer set, where the primers were isolated and readily definable for their sequence structure. For example, Hurteau et al. (Anal Biochem. 307:304-315 (2002)) disclose random primers that are mRNA specific in a heterogeneous nucleic acid background. Because the claimed fragments are not a contribution over the prior art, the claimed invention does not solve a problem over the prior art and is not considered as meeting the unity of invention requirement.

5. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 8-10, 12, 14, 18, and 19 drawn to an isolated polynucleotide comprising SEQ ID NO: 8 or a fragment, an expression vector containing the polypeptide, a host cell transformed with the expression vector, a process for making a polypeptide from the polynucleotide of SEQ ID NO: 9 or 13 or fragments thereof, a medicament of the polynucleotide comprising SEQ ID NO: 8, a pharmaceutical composition comprising the polynucleotide comprising SEQ ID NO:8, and a pharmaceutical composition comprising the polynucleotide comprising SEQ ID NO:8 for treating a proliferative disease.

Group II, claim(s) 6, 7, 13, 15, 20, drawn to an isolated polypeptide comprising the sequence SEQ ID NO: 14 or fragments, a medicament of the polypeptide of SEQ ID NO: 14, a pharmaceutical composition comprising the polypeptide comprising SEQ ID NO:14, a pharmaceutical composition comprising the polypeptide of SEQ ID NO:14 for treating a proliferative disease.

Group III, claim(s) 11, drawn to an antibody or antigen binding fragment thereof which binds the protein sequence of SEQ ID NO: 14 but not the sequence of ID NO: 10.

Group IV, claim(s) 18, drawn to a method for identifying compounds capable of binding human GHRH and modulating cell proliferation comprising contacting a polypeptide encoded by the polynucleotide of SEQ ID NO:9 or 13.

Group V, claim(s) 21, drawn to a method of treating a proliferative disease in a warm-blooded animal comprising administering a polynucleotide comprising SEQ ID NO:8.

Group VI, claim(s) 22, drawn to a method of treating a proliferative disease in a warm-blooded animal comprising administering a polypeptide comprising SEQ ID NO:14.

6. Three different products are presented in Groups I-III. These three products do not share a common property or activity and do not share common core structures. The polynucleotide of Group I, the polypeptide product of Group II, and the antibody of Group III are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the polypeptide is made by translation of mRNA, and the antibody is raised by immunization. Furthermore, the polynucleotide can be used for hybridization screening, the polypeptide can be used for methods of purifying the antibody, and the antibody can be used to immunopurify the polypeptide, for example. The examination of all groups would require different searches in the patent literature and the scientific literature and would require the consideration of different patentability issues.

7. Inventions of Groups I and IV, Groups I and V, and Groups II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can

be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of treating a proliferative disease (Groups V and VI) can be practiced with a materially different product than the polynucleotide or polypeptide, such as for example, chemotherapy, or an antibody specific for an antigen relevant to the proliferative disorder, or a small molecule drug designed for targeting the particular proliferative disorder. As for the method identifying compounds capable of binding GHRH and modulating cell proliferation, the method could be practiced with a materially different product than the polynucleotide of SEQ ID NO: 9 or 13 such as for example a cell or cell line expressing GHRH and measuring the biological effect of the candidate compound on the cell based on a readout of a change in a cellular function or activity or expression of a molecule. The examination of all groups would require different searches in the patent literature and the scientific literature and would require the consideration of different patentability issues.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER